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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/596,224 | 06/05/2006 | Frode Brakstad | VITL0101PUSA | 3744 |
| 22045 | 7590 | 10/01/2008 | EXAMINER | |
| BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075 | | | HUANG, GIGI GEORGIANA | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1612 | | |
| | | MAIL DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/596,224 | BRAKSTAD ET AL. |
| | Examiner | Art Unit |
| | GIGI HUANG | 1612 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 June 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8 and 11-14 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-8 and 11-14 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/16/2008</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The response filed June 10, 2008 has been received, entered and carefully considered. The response affects the instant application accordingly:
 - a. Claims 1-4 have been amended from the originally prosecuted claims.
 - b. Claim 9-10 has been cancelled previously.
 - c. Claim 11 has been added and amended from the originally prosecuted claims.
 - d. Claim 12-14 have been added.
2. Claims 1-8 and 11-14 are pending in the case.
3. Claims 1-8 and 11-14 are present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
5. All grounds not addressed in the action are withdrawn or moot.
6. New grounds of rejection are set forth in the current office action.

New Grounds of Rejection

7. Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 6-8 and 11-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The term “C₁₋₈ carboxylic acid” is not adequately described to convey what comprises the term “C₁₋₈ carboxylic acid”, if the structure is straight, if it is branched, if it is a single ring, if this more than one ring, if there are substitutions, if there are heterocycles, if it is alkyl, if it is aryl, if there are combinations of rings and branches, it does not begin to adequately describe the term for one skilled in the art to envision. It is unclear what would be encompassed by the terms as addressed in the 112, 2nd paragraph rejection below.

Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description for benzoic acid and to a degree formic-, citric-, lactic-, propionic-, ascorbic-, and fumaric- acid. The formic-, citric-, lactic-, propionic-, ascorbic-, and fumaric- acids are themselves unclear as to what the hyphen is indicating. It is unclear if the hyphens is an indicator for the word “acid” or if it is open to additional substitutions which would not be sufficient written description themselves as species. Based on the compounds identified in the specification, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 6-8 and 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "C₁₋₈ carboxylic acid" is not defined by the claims, the specification does not allow one of ordinary skill in the art to be reasonably apprised of the scope of the invention. It is unclear what is the "C₁₋₈ carboxylic acid" and does not allow one of skill in the art to ascertain the metes and bounds of the invention. For purposes of prosecution, any compound that has eight carbons or less with a carboxylic group will fulfill the claims.

12. Claims 6-8 and 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "dry" is a relative term which renders the claim indefinite. The term "dry" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Most compositions have some degree of moisture unless freeze-dried for instance, which will vary widely, depending

on the working, storage, and processing conditions. It is unclear what the circumstances are, the requisite degree, and does not allow one of skill in the art to ascertain the metes and bounds of the invention.

Additionally, the term “dry weight of the supplement” is not defined by the claims, the specification does not allow one of ordinary skill in the art to be reasonably apprised of the scope of the invention. It is unclear what is the “dry weight of the supplement” and if the amounts addressed, include or exclude the vitamins as part of the supplement weight stipulated in the claims. It is also unclear what the “dry weight” would be as most compositions have varying degrees of moisture depending on the working, storage, and processing conditions. It is unclear what the circumstances are and does not allow one of skill in the art to ascertain the metes and bounds of the invention.

For purposes of prosecution, any amount of the components will apply to the claims.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 6 -8 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (U.S.Pat Pub. No. 2002/0150653).

Bailey et al. teaches the concept of a food, feed, and vitamin preparations comprising folates and multivitamins. The compositions were preferably stored with

antioxidants and reducing agents to extend shelf life. The pH of the final composition can be optimized based on the desired stability properties, preferably with an acidity less than about pH 4. The compositions exemplified comprised citric acid, ascorbic acid, vitamin E, pyridoxine (vitamin B6), folic acid (vitamin B9), vitamin B12 (cyanocobalamin), ferrous fumarate, and silica (desiccant). Bailey et al. also teaches the method of administering the compositions to humans and animals, including horses, for the treatment of conditions including intestinal malabsorption, increasing the dietary intake of folate which improves performance as it would improve immune response and reduce risks to cancer, peripheral vascular disease, and nervous system disorders as Bailey teaches that a deficiency in folate would result in a susceptibility to these conditions (see full document, specifically Abstract, Paragraph 3-4, 7, 11, 15-21, 30-36, 42-40).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Response to Arguments

15. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Applicant's arguments filed 6/10/2008 have been fully considered but they are not persuasive. Applicant arguments are not commensurate in scope with the claims. The art meets the composition recitations of the claims.

Accordingly, the rejection is maintained.

16. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the term "C₁₋₈ carboxylic acid".

Applicant's arguments filed 6/10/2008 have been fully considered but they are not persuasive. Applicant arguments are not commensurate in scope with the claims. The art meets the composition recitations of the claims.

Accordingly, the rejection is maintained.

17. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the term "dry weight".

Applicant's arguments filed 6/10/2008 have been fully considered but they are not persuasive. Applicant arguments are to other applications which do not address how the term is view in the instant application. Additionally, the specification recites pH ranges when used in water which is not dry, and the claims are open language which allows for carriers and solvents which goes to the indefinite of "dry weight" and "dry weight of the composition" and it is not clear what forms (e.g. powder verses solution) or components the composition is restricted to.

Accordingly, the rejection is maintained.

18. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (U.S.Pat Pub. No. 2002/0150653).

Applicant's arguments filed 6/10/2008 have been fully considered but they are not persuasive. Applicant arguments that Bailey does not teach a "C₁₋₈ carboxylic acid"

is not persuasive as directed by the specification and current claims, citric and ascorbic acids are such acids and are present in the Bailey reference. The other components are present in the reference as recited previously and above, due to the 112 2nd rejection for purposes of prosecution, any amount of the components will apply to the claims.

Accordingly, the rejection is maintained.

Conclusion

19. Claims 1-8 and 11-14 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612